IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES LLC, Plaintiffs, v. L'ORÉAL USA, INC., Defendant.	)	C.A. No. 17-868-CFC-SRF **PUBLIC VERSION**

L'ORÉAL USA'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS SUMMARY JUDGMENT MOTION OF INDEFINITENESS OF THE DERMAL CELL ADENOSINE CONCENTRATION CLAIM LIMITATION

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Dated: September 11, 2020

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TABLE OF EXHIBITS[1]

Exhibit No.	Document
1	U.S. Patent No. 6,423,327, issued to Dobson, Jr. et al. on July 23, 2002
2	U.S. Patent No. 6,645,513, issued to Dobson, Jr. et al. on November 11, 2003
5	Declaration of Gerald B. Kasting, Ph.D., containing true and correct excerpts from the Expert Report of Professor Gerald B. Kasting, Ph.D., dated June 26, 2020
7	Declaration of Gerald B. Kasting, Ph.D., containing true and correct excerpts from the Reply Expert Report of Professor Gerald B. Kasting, Ph.D., dated August 7, 2020
8	Summary Report for Adenosine Formulation Testing of Edward Kisak, dated June 26, 2020
11	Excerpts from the Expert Report of Bozena Michniak-Kohn, Ph.D., dated June 26, 2020
12	Excerpts from the Rebuttal Expert Report of Bozena Michniak-Kohn, Ph.D. Regarding Validity, dated July 21, 2020
17	Excerpts from the deposition transcript of James Dobson, taken May 27, 2020
20	Excerpts from the deposition transcript of Edward Kisak, Ph.D., taken August 12, 2020
22	Excerpts from the deposition transcript of Bozena Michniak-Kohn, Ph.D., taken August 18, 2020
32	Parties' Joint Claim Construction Brief (D.I. 97), filed March 6, 2020
33	Excerpts from the Claim Construction hearing transcript, dated April 6, 2020

[1] "Ex. __" refers to exhibits attached to the Declaration of Nicholas A. Tymoczko in Support of L'Oréal USA, Inc.'s *Daubert* and Summary Judgment Motions, filed concurrently herewith.

I. THE PATENTS-IN-SUIT, CLAIM CONSTRUCTION, AND THE INTRINSIC RECORD

1. United States Patent Nos. 6,423,327 ("the '327 patent") and 6,645,513 ("the '513 patent") (together, the "patents-in-suit") both claim priority to the same parent patent application filed on October 26, 1998.

2. Claim 1 is the sole independent claim of both patents-in-suit, and recites: "A method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin, without increasing dermal cell proliferation, the method comprising topically applying to the skin a composition comprising a concentration of adenosine in an amount effective to enhance the condition of the skin without increasing dermal cell proliferation, ***wherein the adenosine concentration applied to the dermal cells is [numerical concentration].***" (Ex. 1, 10:17-26 (reciting 10^{-4} M – 10^{-7} M for the numerical concentration);[2] Ex. 2, 10:17-26 (reciting 10^{-3} M – 10^{-7} M for the numerical concentration).).

3. The remaining claim terms of the patents-in-suit all depend from claim 1 and therefore contain the same claim limitations as claim 1.

[2] For ease of reference, the phrase emphasized is referred to as the "concentration limitations." Unless otherwise noted, all emphases have been added and all internal citations, modifications, and quotations have been omitted. The patents-in-suit share a specification and citations are generally provided for the '327 patent only.

4. Consistent with Plaintiffs' proposed construction, the Court construed the concentration limitations ("wherein the adenosine concentration applied to the dermal cells is [numerical concentration]") as "looking at the concentration as it is applied to the dermal cells." (Ex. 33 at 57:17-18; *see also* Ex. 32 at 1, 6; *see also* Ex. 33 at 10:25-11:3 ("[S]o you measure the amount of adenosine that gets to those dermal cells."), 56:19-58:16; D.I. 114.)

5. Neither the claims, the specification, nor the prosecution history provide any description regarding how to determine the adenosine concentration that is "applied to the dermal cells" following topical application to the skin, and thus do not identify any testing methodology to be used to make this assessment. (*See generally* Ex. 1; Ex. 2; Ex. 5, ¶ 249; Ex. 7, ¶ 100; Ex. 17 at 176:5-12, 177:4-8; Ex. 22 at 80:14-22, 81:18-20.)

6. In the 1997-1998 time period, there were a number of methods that could be used to attempt to assess the concentration of a compound at different layers of the skin, including *in vivo* methods such as punch biopsies and microdialysis (Ex. 5, ¶ 250; Ex. 7, ¶ 98; Ex. 22 at 275:3-276:12) as well as *in vitro* permeation testing (Ex. 5, ¶ 250).

II. THERE ARE MULTIPLE TESTING METHODOLOGIES THAT GIVE DIFFERENT RESULTS

7. Plaintiffs have relied on *in vitro* permeation testing to attempt to show infringement of the concentration limitations of the patents-in-suit. (Ex. 5, ¶ 250; Ex. 11, ¶¶ 70-71.)

8. The patents-in-suit do not mention *in vitro* permeation testing at all, and thus do not describe such testing as an appropriate methodology to use to determine any claimed concentration, much less prescribe parameters to be used for such testing. (Ex. 5, ¶ 250; Ex. 22 at 81:18-20; *see generally* Exs. 1-2.)

9. *In vitro* permeation testing does not involve topically applying a composition to intact unbroken skin.

10. In the 1997-1998 time period, there were multiple, different methods available for conducting *in vitro* permeation studies. (Ex. 12, ¶ 177; Ex. 20 at 43:15-22, 51:17-23; Ex. 5, ¶¶ 250-55.)

11. In conducting *in vitro* permeation tests, a scientist can choose, for example, different kinds of skin samples, types of diffusion cells, periods of time to measure the diffusion, and materials for labeling the adenosine for measurement. (Ex. 5, ¶ 251; Ex. 20 at 40:22-41:9, 42:11-16, 42:23-43:14; Ex. 17 at 179:14-17, 180:7-12.)

12. *In vitro* permeation testing may be conducted with cadaver skin or surgically excised tissue (and stored under different conditions, *e.g.*, fresh or

frozen); the skin may have different thicknesses and come from different parts of the body (*e.g.*, abdomen, back, breast, or arms); and the skin sample can have different qualities depending on the donor, including their gender, race, and age. (Ex. 5, ¶ 251, 253-54; Ex. 20 at 40:22-41:9, 42:11-16, 42:23-43:14; Ex. 17 at 192:1-10; Ex. 22 at 86:12-15, 87:10-14, 87:20-88:14.)

13. *In vitro* permeation testing may be conducted with diffusion cells having different designs, including configuration (*e.g.*, static or flow-through) and materials (*e.g.*, glass, Teflon, stainless steel, or plastic), and the amount of applied dose, the duration of exposure, and the type of labeled molecule may all vary. (Ex. 5, ¶¶ 251-55; Ex. 20 at 42:11-16, 43:10-14; Ex. 17 at 179:14-17, 180:7-12.)

14. The different parameters that may be used for *in vitro* permeation testing lead to significantly different results, including with respect to whether the limitations of the claims of the patent-in-suit are met or not. (Ex. 5, ¶¶ 251-55; Ex. 7, ¶ 98; Ex. 17 at 192:1-10, 193:5-24, 348:2-349:8; Ex. 22 at 86:12-15, 87:10-14, 87:20-88:22; 112:22-113:3.)

15. Dr. Dobson testified: "The operator, the type of tissue used, the conditions under which the apparatus was utilized, the temperature, the pressure exerted to the top chamber. All those are factors that could affect the results." (Ex. 17 at 348:2-349:8.)

16. For the piece of skin used, there is donor-to-donor variability, and the age, gender, and race of the donor as well as the location from which the skin is taken will affect its permeability. (Ex. 5, ¶¶ 253-54; Ex. 17 at 192:1-10; Ex. 22 at 86:12-15, 87:10-14, 87:20-88:14.)

17. Both Dr. James Dobson and Dr. Bozena Michniak-Kohn acknowledged that the amount of product applied and the duration of exposure of the skin to the composition will affect the concentration of adenosine permeating the skin. (Ex. 17 at 193:5-24; Ex. 22 at 88:15-22, 112:22-113:3; Ex. 5, ¶ 255.)

18. Dr. Michniak-Kohn has not disputed Dr. Gerald Kasting's opinions that varying the available parameters for *in vitro* permeation testing will affect the results of the testing. (*See* Ex. 5, ¶¶ 253-55; Ex. 12, ¶¶169-180; Ex. 7, ¶¶ 98-99.)

19. Plaintiffs' own *in vitro* permeation testing of L'Oréal USA products shows that, when the same product is tested multiple times with different tissue donors, the mean values reported for the adenosine concentration delivered to the dermis may be inside the scope of the claims for testing performed on one tissue donor and outside the scope of the claims for testing performed on another tissue donor. (Ex. 20 at 174:24-5; *id.* at 167:13-24, 200:15-25, 201:7-14; Ex. 7, ¶ 99 & n.63, Appendix D.)

20. In fact, Dr. Kisak testified that, "depending on the skin donor used, the same L'Oréal product may be found to deliver a concentration of adenosine to the dermis of greater than 10 to the minus 7 molar or less than 10 to the minus 7 molar." (Ex. 20 at 167:13-24, 200:15-25, 201:7-14.)

21. Plaintiffs' experts did not dispute the veracity of Appendix D to Dr. Kasting's reply report (Ex. 7) regarding Plaintiffs' infringement testing results at their depositions.

22. The results for individual replicates of a given test performed by Dr. Kisak involving the same skin donor often varied substantially, such that some replicates were above 10^{-7} M and some were below for adenosine concentrations at the dermis. (*See, e.g.*, Ex. 20 at 208:8-25; Ex. 8 at 18-20; Ex. 7, ¶ 99 & n.64.)

23. In the 1997-1998 time period, there were other methods beyond *in vitro* permeation testing (also known as Franz diffusion cell testing) that could be used to attempt to assess the concentration of a compound at different layers of the skin, including *in vivo* methods such as punch biopsies and microdialysis. (Ex. 5, ¶ 250; Ex. 7, ¶ 98; Ex. 22 at 275:3-276:12.)

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CERTIFICATE OF SERVICE

I hereby certify that on September 11, 2020, a true and correct copy of the foregoing document was filed with the Clerk of Court via CM/ECF which will send notification of such filing to counsel of record and I further certify that a true and correct copy of the foregoing document was caused to be served on the following counsel of record as indicated:

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

The foregoing L'ORÉAL USA, INC.'S CONCISE STATEMENT OF FACTS IN SUPPORT OF SUMMARY JUDGMENT MOTION OF INDEFINITENESS OF THE DERMAL CELL ADENOSINE CONCENTRATION CLAIM LIMITATION complies with the type-volume limitations of Paragraph 19(f) of the Scheduling Order (D.I. 46). The text of this statement, including footnotes, was prepared in Times New Roman 14-point. According to the word processing system used to prepare it, this statement contains 1,277 words, excluding the case caption, tables, and signature block.

September 11, 2020

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